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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,398	03/11/2005	Yukitsuka Kudo	740630-94	2825

22204 7590 12/22/2006  
NIXON PEABODY, LLP  
401 9TH STREET, NW  
SUITE 900  
WASHINGTON, DC 20004-2128

EXAMINER
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CHU, YONG LIANG

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/527,398

Applicant(s)

KUDO ET AL.

Examiner

Yong Chu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 and 26-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, and 25 is/are rejected.
- 7) ☒ Claim(s) 1-9, and 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/05, and 1/12/06</u> .                                     | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

Claims 1-35 are currently pending in the instant application.

### *Information Disclosure Statement*

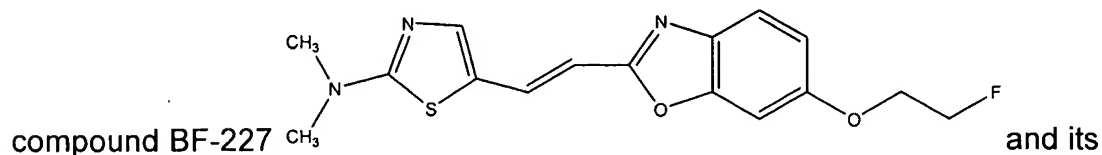
Applicant's Information Disclosure Statements, filed on 8 June 2005, and 12 January 2006 have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

### *Priority*

This application is a 371 of PCT/JP04/11546 filed on 11 August 2004, and claims the benefit of Japan Patent Application 2003-293056, filed on 13 August 2003. ***The priority of PCT/JP03/15229 filed on 28 November 2003 is not acknowledged because it does not meet the requirement of 35 USC 119 (a-d).***

### *Response to Lack of Unity*

The response to the restriction request with provisionally election of Group III (claims 1-9, and 25 *without traverse* by Applicants' representative, Donald R. Studebaker dated on 25 October 2006, has been considered. Due to many prior art hits within the elected scope of invention, Applicant further provided the most significant



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associated definitions related to substituents **m** as 1-4, **A** and **X** is N, **Y** is CH and **Z** is O or S dated on 13 December 2006 for further search and examination purpose.

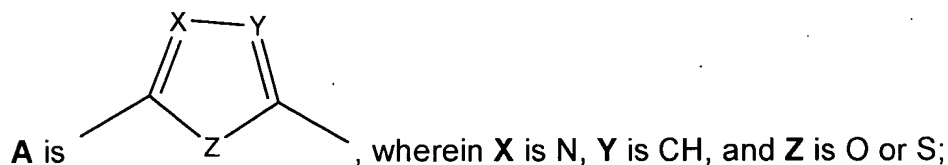
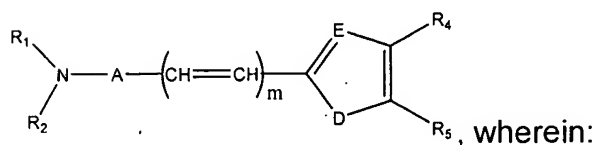
### ***Status of the Claims***

Claims 10-24, and 26-35 are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement dated on 25 October 2006. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and/or element and would require separate search considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

### **Elected Subject Matter**

The scope of the invention of the elected subject matter is as follows:

A compound, a salt or solvate thereof of Formula (I)



**D** is O or S; **E** is N; **m** is 1;

**R**<sup>1</sup> and **R**<sup>2</sup> are hydrogen, or C<sub>1-4</sub> alkyl;

**R**<sup>4</sup> and **R**<sup>5</sup> together form a benzene ring which is optionally substituted with one to four substituents selected from NO<sub>2</sub> and O-C<sub>1-4</sub>alkyl, wherein the C<sub>1-4</sub>alkyl is optionally

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substituted with halogen(s), or phenyl, with the proviso that when  $m$  is 0 and when  $R_4$  and  $R_5$ , together, form a benzene ring, the ring  $A$  is not a benzene ring.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-9 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The withdrawn compounds and process of use contain method claims and compounds with varying functional groups, which are chemically recognized to differ in structure, function, or reactivity.

Therefore, claims 1-9 and 25 will be examined on the merits.

### ***Specification***

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

The disclosure is objected to because of the following informalities: the disclosure contains non-English phrases, such as definition of compounds of BF-255, 256 and 257 on page 31-32 of the Specification. Applicant needs to correct all related errors. Appropriate correction is required.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: inappropriate Markush claim of  $R_4$  and  $R_5$  on lines 14-15 of page 94 of the specification "...O-C<sub>1-4</sub>alkyl, wherein the C<sub>1-4</sub>alkyl is optionally substituted with halogen(s), and phenyl, with the proviso that when  $m$  is 0 and...". "and" should be "or". Appropriate correction is required.

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Claim 3 is objected to because of the following informalities: compound codes such as BF-185, and BF-187 should not be in claim. Chemical name or formula is allowed in claim. Appropriate correction is required.

Claims 1-9 and 25 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "the compound is labeled" lacks of definition in the specification, and render indefinite.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "radionuclide" lacks of definition in the specification, and render indefinite.

***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

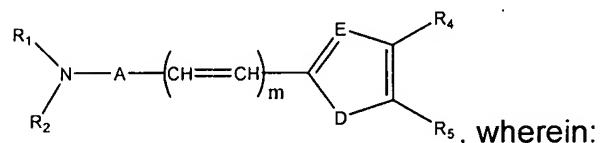
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-9, and 25 are rejected under 35 U.S.C. 102 (b) as being anticipated by Oehlschlaeger et al., U.S. Patent No. 3,816,138.

Applicants' claims relate to a compound, a salt or solvate thereof of Formula (I)

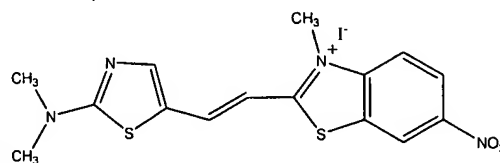


**A** is , wherein **X** is N, **Y** is CH, and **Z** is O or S;

**D** is O or S; **E** is N; **m** is 1;

**R**<sup>1</sup> and **R**<sup>2</sup> are hydrogen, or C<sub>1-4</sub> alkyl;

**R**<sup>4</sup> and **R**<sup>5</sup> together form a benzene ring which is optionally substituted with one to four substituents selected from NO<sub>2</sub> and O-C<sub>1-4</sub>alkyl, wherein the C<sub>1-4</sub>alkyl is optionally substituted with halogen(s), or phenyl, with the proviso that when **m** is 0 and when **R**<sub>4</sub> and **R**<sub>5</sub>, together, form a benzene ring, the ring **A** is not a benzene ring.



Oehlschlaeger et al. disclose a compound

(CAS CN 41474-49-1) in column 11 as compound 38 in U.S. Patent No. 3,816,138.

This compound reads on the instantly claimed genus as a **salt** of the claimed compounds of Formula (I), wherein:

**A** is , wherein **X** is N, **Y** is CH, and **Z** is S;

**D** is S; **E** is N; **m** is 1;

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$R^1$  and  $R^2$  are  $C_{1-4}$  alkyl;

$R^4$  and  $R^5$  together form a benzene ring which is optionally substituted with one  $NO_2$ .

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

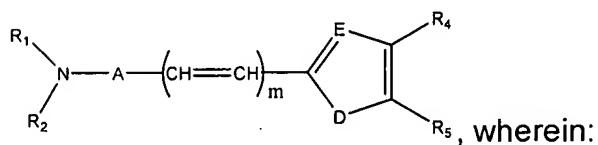
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

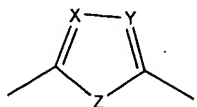
Claims 1-9, and 25 are rejected under 35 U.S.C. 103 (a) as unpatentable over Oehlschlaeger et al., U.S. Patent No. 3,816,138.

Applicants' claims relate to a compound, a salt or solvate thereof of Formula (I)





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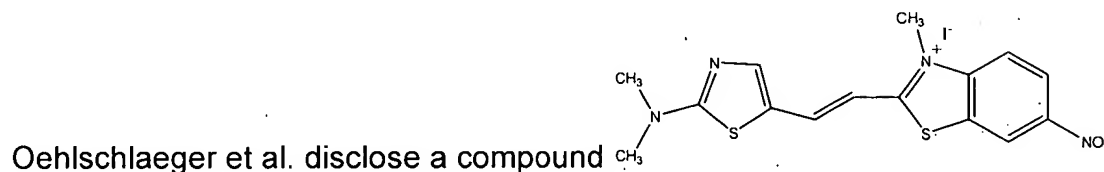
A is , wherein X is N, Y is CH, and Z is O or S;

D is O or S; E is N; m is 1;

R<sup>1</sup> and R<sup>2</sup> are hydrogen, or C<sub>1-4</sub> alkyl;

R<sup>4</sup> and R<sup>5</sup> together form a benzene ring which is optionally substituted with one to four substituents selected from NO<sub>2</sub> and O-C<sub>1-4</sub>alkyl, wherein the C<sub>1-4</sub>alkyl is optionally substituted with halogen(s), or phenyl, with the proviso that when m is 0 and when R<sub>4</sub> and R<sub>5</sub>, together, form a benzene ring, the ring A is not a benzene ring.

Determination of the scope and content of the prior art (MPEP §2141.01)



(CAS CN 41474-49-1) in column 11 as compound 38 in U.S. Patent No. 3,816,138.

This compound is related to the instantly claimed genus as a salt of the claimed compounds of Formula (I).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the Oehlschlaeger compound and the instantly claimed compounds, is that the prior art teaches a compound with R<sup>1</sup> and R<sup>2</sup> are both methyl group, and does not teach the compounds having R<sup>1</sup> and R<sup>2</sup> as hydrogen or C<sub>2-4</sub> alkyl group.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

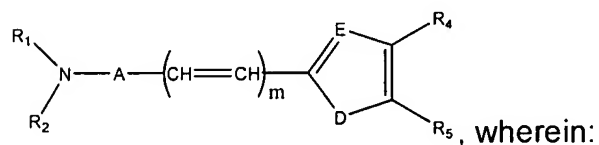
The instantly claimed compounds would have been obvious over

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The prior art compounds, wherein  $R^1$  and  $R^2$  is  $CH_3$  vs. hydrogen or  $C_{2-4}$  alkyl, because one skilled in the art would have been motivated to prepare homolog of the compounds with  $R^1$  and  $R^2$  as  $C_{1-4}$  alkyl with the expectation of success. To those skilled in the chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claims 4-9, and 25 are rejected under 35 U.S.C. 103 (a) as unpatentable over Oehlschlaeger et al., U.S. Patent No. 3,816,138.

Applicants' claims relate to a compound, a salt or solvate thereof of Formula (I)



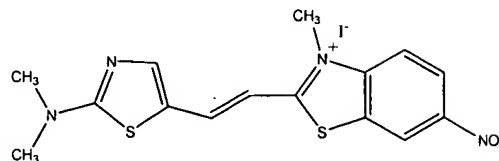
$A$  is , wherein  $X$  is N,  $Y$  is CH, and  $Z$  is O or S;

$D$  is O or S;  $E$  is N;  $m$  is 1;

$R^1$  and  $R^2$  are hydrogen, or  $C_{1-4}$  alkyl;

$R^4$  and  $R^5$  together form a benzene ring which is optionally substituted with one to four substituents selected from  $NO_2$  and  $O-C_{1-4}$ alkyl, wherein the  $C_{1-4}$ alkyl is optionally substituted with halogen(s), or phenyl, with the proviso that when  $m$  is 0 and when  $R_4$  and  $R_5$ , together, form a benzene ring, the ring  $A$  is not a benzene ring.

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Determination of the scope and content of the prior art (MPEP §2141.01)

Oehlschlaeger et al. disclose a compound (CAS CN 41474-49-1) in column 11 as compound 38 in U.S. Patent No. 3,816,138.

This compound is related to the instantly claimed genus as a salt of the claimed compounds of Formula (I).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the Oehlschlaeger compound and the instantly claimed compounds, is that the prior art teaches a non-radio labeled compound, and does not teach the compounds with radio labeled. However, radio labeled a known compound is obvious to one skill in the chemical art. For example, GE Healthcare provides custom label service to scientists, and the methods are well-known in the art (see GE Healthcare catalog).

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compounds would have been obvious over the prior art compounds, because radio-labeling a known compound is obvious to one skill in the chemical art. For example, GE Healthcare provides custom label service to scientific community, and the methods are well-known in the art (see GE Healthcare catalog).

**Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, and 25 of this application conflict with claim 1 of Application No.

10/524,691 filed on 29 August 2003. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 1-9, and 25 provisionally rejected on the ground of nonstatutory double patenting over claim 1 of copending Application No. 10/524,691. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application 10/524,691 and would be covered by any patent granted on that copending application since the referenced copending application and the instant

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application are claiming common subject matter, as follows: the co-pending Application 10/524,691, Formula (I) of claim 1 conflicts subject matter with the instant application, wherein  $m=1-4$ ,  $A$  is ring (ii),  $R_3$  is  $NH_2$ ,  $NH(C_{1-4}alkyl)$ ,  $N(C_{1-4}alkyl)_2$ ,  $R_1$  and  $R_2$  together form benzene with substituents of  $R_4$ .

### ***Conclusion***

Claims 1-9 and 25 are rejected.

Claims 1-9 and 25 are objected.

### ***Telephone Inquiry***

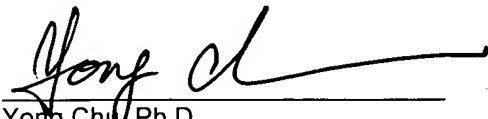
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759.

The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

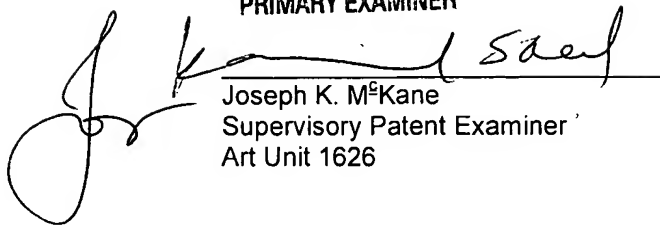
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Yong Chu', written over a horizontal line.

Yong Chu, Ph.D.  
Patent Examiner  
Art Unit 1626

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Joseph K. McKane', written over a horizontal line.

Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626